

## REMARKS

### **I. Amendments**

Claims 1 and 13 have been cancelled, claims 3-6 and 8 have been amended and claims 23 and 24 have been added by this amendment.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No change of inventorship is necessitated by this amendment.

### **II. Discussion of the Rejection under 35 U.S.C. Sec. 102(b)**

Claims 1, 3-5, 8 and 13 stand rejected under 35 U.S.C. Sec. 102(b) as being unpatentable over Ueda *et al.* (EP 0 394 050 A2). Applicants assert that the rejection is moot by virtue of the present amendments to the claims.

By this amendment, claims 1 and 13 have been cancelled, and the dependency of dependent claims 3-5 and 8 has been modified such that they only depend from claim 2.

Therefore, Applicants respectfully request withdrawal of the Sec. 102 (b) rejection.

### **III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a)**

Claims 1-6, 8, 10, 13, 14, 16 and 18-22 stand rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over Ueda *et al.* (EP 0 394 050 A2). Applicants respectfully traverse the rejection, asserting that the "water-repelling base material" feature of the rejected claims is neither taught nor suggested by the cited reference.

By this amendment, claims 1 and 13 have been cancelled, and the dependency of dependent claims 3-6 and 8 has been modified such that they only depend from claim 2.

Independent claims 2, 14 and 20 specify a coating of a water-repelling base material for the inner face of a freeze-drying container, which is not disclosed in the cited art, as the Examiner has already admitted.

As Applicants have previously indicated, it appears that the Examiner would like to equate the Applicants' coated water-repelling base material with the "second liquid" taught by the cited art.

Also, the Examiner has indicated that "it is the position of the examiner that if the desired active for the formulation is a hydrophobic active, then the skilled practitioner would use a hydrophobic layer in addition to the ice layer". The Applicants dispute that this conclusion would have been drawn by one skilled in the art by reading the cited reference, but even if it were true, it still does not provide Applicants' recited "water-repelling base material". Applicants' reasoning is discussed below.

Reviewing the teachings of the cited reference concerning the layers and their composition in greater detail, one finds that applicable layers for the cited art are discussed at the bottom of page 3 and the top of page 4 of the cited reference. In each recited example, at least one component of the formulation is found in a layer, unless the layer is "plain water, to assist the speed of the freeze-drying process".

In the tenth paragraph on page 4 of the cited reference, it is indicated that, for liquids, "one or more (but not all) may be a pure solvent (generally and preferably water)".

From these teachings one can glean that there can be an additional liquid layer which doesn't contain a component of the formulation, but that additional layer is a solvent, and that solvent is preferably water.

In contrast, the water-repelling base materials of the present invention are coatings for the containers, not components to be freeze-dried, or aids to freeze-drying which will themselves evaporate. Those skilled in the art would comprehend these salient points.

As further proof of the logic under which Applicants disagree with the Examiner's conclusion, Applicants wish to direct the Examiner's attention to Example 4. Note in particular, that in one of the layers (solution 1), ingredients which are lipophilic are not dissolved in a lipophilic solvent. Instead, they are mixed with a surfactant in order to make them water-soluble, as stated below the list of ingredients of solution 1 (Table 4) of the cited reference on page 8. That is to say, the Examples conflict with the conclusion which the Examiner has drawn. So the Examiner's overly broad assumption about the teachings of the cited reference is just plain wrong.

In addition, in order for the recited "water-repelling base material" to be found in the teaching of the cited reference, hydrophobic solvents (which are not even mentioned in the cited reference) would need to equal to water-repelling base materials, as Applicants have defined them in their specification.

Applicants challenge the Examiner to show them examples wherein the water-repelling base materials which Applicants have cited can either act as solvents or assist the speed of the freeze-drying process.

Therefore, the limitation of the water-repelling base material is neither taught nor suggested by the "second liquid" of the cited art. Therefore, Applicants do not believe their methods, as set forth in independent claims 2, 14 and 20 are obvious in light of the cited reference, which does not teach or suggest a water-repelling base material.

Specific water-repelling base materials are cited in dependent claims 6, 19 and 22. These more specific dependent claims could not be considered to be taught by the cited reference by any stretch of the imagination. Should the Examiner choose to maintain the rejection, Applicants respectfully request that the Examiner indicate how these resins are indicated by the cited reference.

Claims 3-6, 8 and 10 depend upon claim 2, claims 16, 18 and 19 depend upon claim 14 and claims 21 and 22 depend upon claim 20. Applicants submit that these more specific dependent claims are also not rendered obvious by the cited reference for the reason provided above.

As there is no teaching, suggestion or even exemplified use of a hydrophobic solvent in the cited reference, and the Applicants' recited water-repelling base materials cannot be equated with hydrophobic solvents even if there was, Applicants respectfully request withdrawal of the Sec. 103(a) rejection.

#### **IV. Discussion of New Claims 23 and 24**

By this amendment, new independent claims 23 and 24 have been added. These claims do not introduce new matter, as they include the limitations of the previous claims 1 and 13, while additionally specifying microcapsular preparations of leuporelin acetate. Support for the new claims may be found at page 9, lines 13-16 *inter alia*.

## V. Conclusion

Reconsideration of the claims and allowance of claims 2-6, 8, 10, 14, 16 and 18-24 is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: October 2, 2003

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